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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,885	07/03/2001	Raghavan Rajagopalan	MRD / 62	2179

7590 03/03/2003  
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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/898,885

Applicant(s)

RAJAGOPALAN ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13,24-30,40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 13,24-30 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**1)** Newly submitted claim 41 is directed to an invention that is independent or distinct from the invention originally claimed and examined for the following reason. Newly presented claim 41 corresponds to original claim 12, which was a non-elected invention (see Group IV of the first Office action). The reasons for the holding of distinctness of the inventions I (elected and examined) and IV (corresponding to newly presented claim 41) are set forth in paragraph **2)a)** of the first Office action. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41 as well as claims 13 and 24-30 (dependent from non-elected claim 41) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

**2)** The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**3)** Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by each of Pochinok et al, Ol'shevskaya et al, Clecak et al, and Leung et al.

Each of the references describes at least one compound which anticipates a compound of instant claim 40. See the descriptions of the references which appear in paragraphs **8)** through **10)** of the first Office action.

Newly presented claim 40 is directed to "a composition comprising a pharmaceutically acceptable formulation" of the compound of original claim 1. The section of the specification which is pertinent to the definition of "a pharmaceutically acceptable formulation" appears at page 15, line 13 *et seq.* The description includes such pharmaceutical formulations as an "aqueous solution or suspension" which "may optionally include buffers" as well as ***the compound alone*** formulated "for oral administration" (which optionally "***may*** also contain flavoring agents and other ingredients"). Page 16, lines 7-8 indicate that the compound *per se* ("a pharmaceutically acceptable formulation") may be put directly on the skin.

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Leung et al at col. 21, lines 22-30 describe a composition of the dye compound of the instant invention in both pharmaceutically acceptable DMSO and "lower alcohol or other completely water-miscible solvents". This "stock solution" can be further diluted "into an aqueous buffer". These formulations anticipate the "pharmaceutically acceptable formulation" of instant claim 40. The intended **pharmaceutical use** recited in claim 40 does not differentiate the **actual composition** of this claim from the composition of Leung et al. Similarly, the compositions of Clecak et al (col. 3, lines 1-9: solution of the compound in ethanol), Pochinok et al ("dyes in solution"), and Ol'shevskaya et al (EtOH solution) anticipate the formulations of instant claim 40.

In view of the description of the "pharmaceutically acceptable formulation" of the instant specification which appears to include **the dye compound alone** as an appropriate "pharmaceutically acceptable formulation", the dye compounds *per se* described in the prior art references are also considered to anticipate the formulation of instant claim 40.

**4)** Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

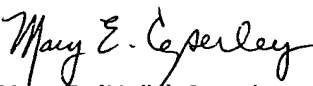
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5) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

March 1, 2003

  
Mary E. (Molly) Ceperley  
Primary Examiner  
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